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(54) Bone Augmenting Implant

(57) The invention relates to a surgical implant 1 for insertion between a bone surface of a bone which has suffered bone loss and a prosthesis shaped to fit the bone before some or all of the bone loss occurred so as to provide a load bearing layer for supporting the prosthesis on the bone surface, the implant comprising a pre-formed, pre-cured spacer of polymeric material of a thickness selected at least partially to augment the bone loss, the spacer having a first surface 2 for presentation to the prosthesis and a second surface 8 for presentation to the bone surface. Each surface may include cavities 7 to increase the cement contacting surface area. The implant is preferably made from a material compatible with bone cement, eg. methyl methacrylate.

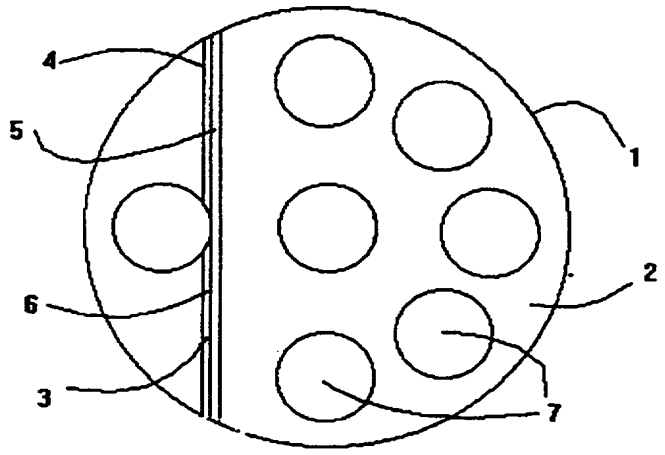

FIG. 1

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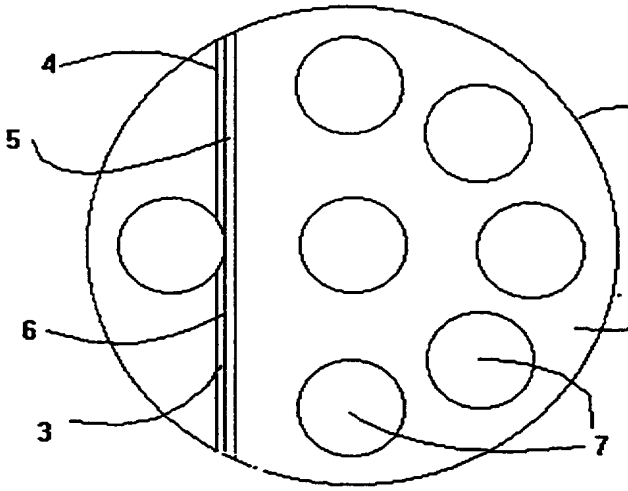

FIG. 1

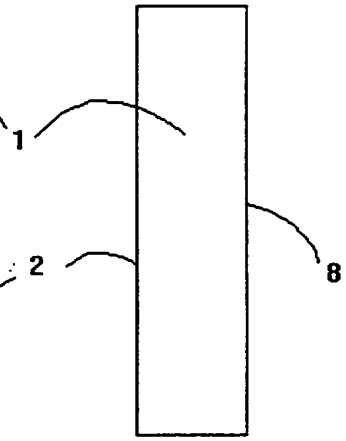

FIG. 2

SURGICAL IMPLANT

The present invention relates to a surgical implant, particularly to an augmentation spacer for compensating bone loss or absence.

The replacement of the whole or parts of a bone surface with prosthetic implants generally requires a surgeon to make one or more resections on the bone surface and to select a prosthetic implant of appropriate size to fit the resected surface. Prosthetic implants are manufactured in a variety of discrete sizes to meet the individual needs of patients.

In some cases, perhaps because of the size of the bone or deterioration of bone material, it is not possible to select a prosthetic implant of the correct size. There may then exist a gap between the bone surface and the selected prosthetic implant. This gap would, if it were allowed to remain, cause laxity or other instability in the joint.

It is becoming increasingly common for patients to have more than one operation on the same joint during the course of their lives. Revision operations commonly lead to problems of the type described above. This is often due to the deterioration of a part of the bone surface after original implantation of a prosthesis.

Currently, there are a number of methods for tackling the problem of augmenting the gap between an inadequate bone surface and a prosthetic implant. None of these methods is entirely satisfactory.

One conventional method involves the use of metal spacers which are designed to be secured to the prosthetic implant and may be secured thereto with a metal retaining screw. This method suffers from two disadvantages. Firstly, the metal-on-metal joints between the spacer and the implant, the spacer and the retaining screw, and the implant and the screw may cause crevice, fretting or other forms of corrosion of the metal. Metal corrosion can cause deterioration of, and instability in, the joint. Secondly, it is expensive for a surgeon to purchase and maintain adequate stocks of the metal spacers in the full range of available sizes. Also, since commercially available prostheses each have their own idiosyncratic features, it is necessary for surgeons to maintain stocks of not just one but all types of commercially available prostheses and spacers, making the cost in some cases prohibitive.

It is also possible to manufacture individual implants which are shaped to meet the requirements of an individual patient. However, the manufacturing of such implants is costly and time-consuming, resulting in delay to the patient's operation.

Bone loss may also conventionally be augmented by bone-grafting. However, the surgical procedure involved is difficult and time-consuming and success rates are not predictably good. This technique is particularly unsuitable in older patients.

Another conventional method for augmenting bone loss involves the use of a workable bone cement to pack the gap between the prosthesis and the bone surface. Although commonly used, this method is difficult to perform cleanly. The bone cement, generally comprising a polymerisable material, a polymerisation initiator and various other minor ingredients, is mixed for a period until the cement becomes workable. It is then applied by means of a spatula, or other suitable implement, to the under-surface of the prosthesis which is to be fitted over the bone surface from which bone loss has occurred. This method has the disadvantage that bone cement is squeezed out from the gap between the prosthesis and the bone surface when the prosthesis is secured to the bone surface. This will alter the thickness of the packed cement, thereby reproducing the very problem which was sought to be solved.

Other prior art relating generally to prosthetic implants combatting or preventing bone loss include EP-A-0518278 and GB-A-1556814. The first of these documents describes flexible prosthetic implants for repairing, replacing or augmenting hard tissue or bone. The flexible implant comprises a plurality of segments that are connected by flexible retainers which enable the segments to be reoriented in relation to one another to accommodate the contour, size and shape of the body part being treated. GB-A-1556814 relates to a prosthetic interpositioning collar for disposition between a metal prosthetic bone implant having a stem and adjacent portions of bone. The object of the invention described in GB-A-1556814 is to provide a means for strengthening the joint between a collar of a bone implant and the cut edge of the bone against which it bears and between the adjacent wall of the bone and inserted stem. However, neither of these documents addresses the problem of how to augment the gap between an inadequate bone surface and a prosthetic implant.

It is therefore an object of the present invention to provide an improved

means for compensating bone loss or absence in prosthetic surgery.

Accordingly, the present invention provides a surgical implant for insertion between a bone surface of a bone which has suffered bone loss and a prosthesis shaped to fit the bone before some or all of the bone loss occurred so as to provide a load bearing layer for supporting the prosthesis on the bone surface, the implant comprising a pre-formed, pre-cured spacer of polymeric material of a thickness selected at least partially to augment the bone from which bone loss has occurred, the spacer having a first surface adapted for presentation to the prosthesis and a second surface for presentation to the bone.

It is envisaged that surgeons will maintain stocks of the surgical implants of the invention in different thicknesses and sizes at relatively low cost. When an operation requiring augmentation of bone loss is performed, surgeons will select a spacer of appropriate size and thickness and apply bone cement to the first surface of the spacer. The spacer can then be mounted on the prosthesis, adhesion between the workable bone cement, the spacer and the prosthesis ensuring that the spacer does not slip out of place when the prosthesis is secured to the bone surface. One or both of the bone surface and the second surface of the spacer will usually also be provided with a quantity of bone cement to assist securement of the prosthesis to the bone surface.

In a preferred embodiment of the invention, the selected thickness of the spacer corresponds to the maximum thickness of the implant. This facilitates insertion of the implant. It is envisaged that implants may desirably be equipped with small ridges or other protuberances designed to cooperate with corresponding troughs or depressions on commercially available prostheses. The word "thickness" as used herein is not intended to refer to or incorporate reference to such features.

It is also a preferred feature of the invention that the first surface of the spacer be substantially parallel to the second surface of the spacer. In this case, the perpendicular distance between the first surface and the second surface is the selected thickness of the spacer and may, in accordance with the preferred embodiment referred to above, also be the maximum thickness of the implant. As will be apparent from the following description, it is envisaged that the first surface of the spacer in particular may not be uniform but may contain troughs or cavities

therein, designed to cooperate with corresponding ridges or protuberances on commercially available prostheses. The use of the word "parallel" herein to describe the spatial relationship between the first and second surfaces of the spacer is not intended to refer to or incorporate reference to such features.

Preferably, the first surface of the spacer has at least one cavity for receiving a workable bone cement therein.

If desired, the second surface of the spacer may also be provided with one or more cavities for receiving a workable bone cement therein.

When at least one cavity is provided on the first surface of the spacer, the cavity may comprise a longitudinal groove adapted for cooperation with a corresponding ridge on the prosthesis. Preferably, the groove has a width of from about 1.0mm to about 3.0mm, for example about 2.0mm. The groove may comprise sloping sides which meet at a common line at the base of the groove, in which case the angle of inclination of the sides of the groove may be from about 20° to about 80°, for example about 60° from the vertical plane bisecting the groove along its length. The angle of inclination of each respective side of the groove may be the same or different, depending on the geometry of the ridge on the particular prosthesis with which the spacer is designed to cooperate. Alternatively, the groove may be a trough with a bottom portion and two side portions, in which case the angle of inclination of the side portions may be, or may approach, 0°. However, it is also possible to provide a groove having a bottom portion and sloping sides.

If present, a longitudinal groove on the spacer is designed to cooperate with corresponding ridges on commercially available prostheses. Accordingly, the implant of the invention may be manufactured with a variety of groove configurations to serve a range of commercial prostheses.

In one preferred embodiment of the invention, the first surface of the implant is circular and the longitudinal groove lies along a chord of the circle.

The implant of the invention is preferably manufactured from the same polymeric material that forms the principal polymeric component of the bone cement used in the operation requiring use of the implant. A preferred material for manufacture of the implant is polymethylmethacrylate. Methylmethacrylate is the monomer material present in most commercially available, unmixed bone cements.

The advantage of manufacturing the implant of the invention from the same polymeric material as is present in commercially available, mixed bone cement is that the chemical bond formed between the bone cement, which is worked into the at least one cavity, if present, and over the surface of the implant, and the implant is very strong. When polymethylmethacrylate is used as the material for the spacer, the bond formed between most methylmethacrylate-based bone cements and the spacer is extremely strong, resulting in a cured integral body comprising the spacer and a polymerised bone cement applied thereto.

In addition to, or instead of, a longitudinal groove, the implant of the invention may comprise on its first surface one or more wells for receiving bone cement therein. The or each well may be of any suitable shape. Circular-rimmed wells are preferred for ease of manufacture. The advantage of such wells is that the effective surface area for bonding contact between the implant and a workable bone cement applied thereto is increased, thereby improving the stability of the implant when secured to the prosthesis. Preferably, a plurality of wells are provided, for example from about two to about fifteen wells are provided on the first surface of the implant. In one preferred embodiment, seven wells and one longitudinal groove are provided on the first surface of the implant. In one preferred embodiment, one well is located centrally on the first surface of the implant, the remaining wells being radially spaced around the central well.

Whilst it is possible to have overlap between the groove, if present, and one or more of the wells, it is preferred for stability reasons that the groove, if present, be left substantially intact. Accordingly, it is preferred to omit wells from any radial position at which such wells would completely overlap the longitudinal groove.

In another preferred embodiment of the invention, bone cement-receiving wells are provided on the second surface of the implant. The number of wells so provided may be the same as or different from the number of wells provided on the prosthesis-contacting surface of the implant. Optionally, corresponding wells on the first and second surfaces of the implant may communicate with each other so that a bore through the implant is provided for receipt of bone cement.

The implant of the invention has applications in many types of prosthetic surgery. One particular application is in knee replacement or revision operations.

When implanting a prosthetic knee, a surgeon must generally make a number of resections, for example five resections, on the distal end of the patient's femur. Frequently, and particularly in the case of revision operations, the posterior femoral condyles have suffered bone loss and require augmentation. Accordingly, one preferred embodiment of the invention is designed to augment the posterior femoral condyles in such circumstances.

However, the implants of the invention may also be used in conjunction with other types of prostheses, such as tibial and acetabular components.

The implant of the invention may be of circular cross-section, which is convenient for the augmentation of posterior femoral condyles. However, cross-sections of alternative shape may be used, so long as the implant of the selected cross-section serves its purpose of augmenting bone loss without introducing excessive instability in the joint. When the implant is used to augment bone loss from other types of bone surface, it may be necessary to select alternative cross-sections to meet the individual requirements of the bone surface in question.

The polymethylmethacrylate, or other polymeric material, from which the implant is manufactured may additionally comprise materials normally present in the components of unmixed bone cement. These materials include methyl methacrylate, hydroquinone, ascorbic acid, N,N-dimethyl-p-toluidine, ethanol, benzoyl peroxide and barium sulphate. The functions of these ingredients are well understood by those skilled in the art. Preferably, however, the implant is manufactured from substantially pure polymeric material, such as polymethylmethacrylate. In some circumstances, it may be preferred to mold the implant directly from a polymerisable material. Conveniently, however, the implant is cut from a length of polymer rod. Most preferably, the implant is manufactured from a material which is pre-certified for purity.

The implant of the invention should be surgically sterile and is preferably sterilised by γ-radiation. Conveniently, the implant of the invention is sold in sterile, sealed packaging to prevent contamination thereof between packaging and use.

The implants of the invention may be manufactured in a variety of discrete thicknesses, optionally corresponding to the stepwise increases in thickness available in commercial prostheses, such as femoral prostheses. For example, the implants of

the invention may be manufactured in 6.0mm, 12.0 mm and 18.0mm thicknesses, and intermediates thereof.

In order that the invention may be clearly understood and fully carried into effect, a particular preferred embodiment thereof will now be described with reference to Figures 1 and 2, in which:

Figure 1 is a top plan view of the first surface of a surgical implant in accordance with a preferred embodiment of the invention; and

Figure 2 is a side plan view of the surgical implant of Figure 1.

It will be understood that the description that follows is given for the purpose of explaining the particular technical features of one preferred embodiment of the invention. Unless indicated otherwise, the description should not be taken as limiting the scope of the invention in any way. In particular, the number and positioning of wells and grooves on the first surface of the surgical implant according to the invention are indicated by way of non-limiting example only.

Referring to Figure 1, a surgical implant 1 is of circular cross-section and is manufactured from polymethylmethacrylate. In the manufacturing process, a disc of the required thickness is cut from a length of pre-formed, pre-cured polymethylmethacrylate rod and is then machined to the required specifications.

The surgical implant 1 has a first surface 2 for presentation to a prosthesis (not shown). The implant 1 is designed to augment one of the posterior femoral condyles of the human knee.

The first surface 2 is provided with a first type of cavity, in the form of a longitudinal groove 3. The longitudinal groove 3 is V-shaped, having two side walls 4 and 5 which are each inclined, in opposite respective directions, at an angle of 60° to the vertical plane bisecting the groove 3 along its base 6. The longitudinal groove is 2.0mm in width and the greatest perpendicular distance from the base 6 to the left hand edge of the implant 1 is 6.5mm. The implant 1 is thus designed for presentation to and cooperation with posterior femoral condylar portions of the commercially available Freeman/Samuelson prothetic femoral knee component. That is to say, the longitudinal groove 3 is designed to cooperate with a corresponding ridge (not shown) on a Freeman/Samuelson knee (not shown).

In use of the implant, a workable bone cement is applied to the first surface

2 of the implant 1 and is worked into the longitudinal groove 3. When the first surface 2 of implant 1 is is presented to a prosthesis, a strong bond is formed therebetween. The prosthesis may then be safely and securely attached to the bone surface.

The second surface 2 of the prosthetic implant 1 is further provided with a second type of cavity, in the form of a series of wells 7. Each well 7 is a dished cavity of circular cross section. The wells 7 are arranged with one well 7 disposed at the centre of the first surface 2 of the implant 1 and with the remaining wells 7 disposed around the periphery thereof. The placement of wells 7 is selected to avoid complete overlap between any particular well 7 and the longitudinal groove 3. This is to avoid the introduction of any laxity between the longitudinal groove 3 and the corresponding ridge (not shown) of a prosthesis.

In use of the implant 1, a workable bone cement is applied to the first surface 2 of the implant 1 and is worked into the wells 7. The resulting bond between the implant 1 and a prosthesis is strengthened because of the increased surface area contact provided by wells 7.

It will be understood that the wells 7 can be formed in any suitable number, orientation, configuration and shape.

Referring to Figure 2, the first surface 2 of implant 1 is opposed by a second surface 8 thereof for presentation to the bone surface. The second surface 8 may also, if desired, be provided with one or more cavities to aid adhesion to the bone surface when a workable bone cement is applied to the second surface 8. However, none are shown on the embodiment shown in Figure 2.

The implant 1 may be manufactured in a series of discrete thicknesss. These may correspond to the typical gradations of thickness available in commercial knee prostheses. Intermediate thicknesses may also be produced.

CLAIMS:

1. A surgical implant for insertion between a bone surface of a bone which has suffered bone loss and a prosthesis shaped to fit the bone before some or all of the bone loss occurred so as to provide a load bearing layer for supporting the prosthesis on the bone surface, the implant comprising a pre-formed, pre-cured spacer of polymeric material of a thickness selected at least partially to augment the bone from which bone loss has occurred, the spacer having a first surface adapted for presentation to the prosthesis and a second surface for presentation to the bone.

2. A surgical implant according to claim 1, wherein the selected thickness of the spacer corresponds to the maximum thickness of the implant.

3. A surgical implant according to claim 2, wherein the first surface of the spacer is substantially parallel to the second surface of the spacer.

4. A surgical implant according to claim 3, wherein the perpendicular distance between the first surface and the second surface is the selected thickness of the spacer and hence the maximum thickness of the implant.

5. A surgical implant according to any one of claims 1 to 4, wherein the implant is manufactured from the same polymeric material which forms the principal polymeric component of a bone cement usable in an operation requiring use of the implant.

6. A surgical implant according to any one of claims 1 to 5, wherein the implant is manufactured from polymethylmethacrylate.

7. A surgical implant according to any one of claims 1 to 6, wherein the first surface of the spacer has at least one cavity for receiving a workable bone cement therein.

8. A surgical implant according to claim 7, wherein the at least one cavity of the first surface of the spacer comprises a longitudinal groove.

9. A surgical implant according to claim 8, wherein the longitudinal groove is adapted for cooperation with a corresponding ridge on the prosthesis.

10. A surgical implant according to any one of claims 1 to 9, wherein the second surface of the spacer is provided with at least one cavity for receiving a workable bone cement therein.

11. A surgical implant according to any one of claims 7 to 10, wherein at least one cavity is provided on each of the first and second surfaces of the implant, at least one cavity on the first surface of the implant communicating with at least one cavity on the second surface of the implant so that at least one bore is provided through the implant.

12. A surgical implant according to any one of claims 7 to 11, wherein the at least one cavity on the first or second surface of the implant comprises one or more wells for receiving bone cement therein.

13. A surgical implant according to any one of claims 1 to 12, which is of one-piece construction.

14. A sterile, sealed package containing an implant according to any one of claims 1 to 13.

15. A set of packages according to claim 14, each package containing an implant of different thickness.

16. The use of an implant according to any one of claims 1 to 13 in a surgical procedure requiring implantation of a prosthesis.

17. A set of sterile surgical implants according to any one of claims 1 to 13, each implant in the set being of successively larger stepwise thickness.

18. A set according to claim 15, wherein the stepwise increase in thickness corresponds to the stepwise increase in thickness of a commercially available prosthesis.

19. A surgical implant constructed and arranged substantially as described herein with reference to Figures 1 and 2.

The Patent Office

12

Application No: GB 9723938.8 **Examiner:** Anwar Gilani
Claims searched: 1-15 and 17-19 **Date of search:** 2 March 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): RAG, RAJ, RAP

Int Cl (Ed.6): A61F 2/28, 2/30

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB1556814	(HOWMEDICA) whole document, particularly p.2 l.21-27	1
X	EP0518278 A1	(UNITED STATES SURGICAL CORPORATION) column 1 l.5-9 and column 6 l.43-54	1,5,6

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.